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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,839	03/29/2001	Hong Ma	PSU-0020	3569

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/821,839	MA, HONG	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 26, 2003 has been entered.

Claims 1-8 and 12-13 are pending and are examined.

Claims 1-8 are currently amended.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-3, 5 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed April 25, 2003.

Applicant's arguments filed September 26, 2003, have been fully considered but they are not persuasive.

Claims 1-3 and 5 as amended are now drawn to isolated nucleic acid molecules encoding a polypeptide comprising an amino acid sequence greater than 70% or at least 95% identical to amino acids 361 through 521 of SEQ ID NO:2, and an isolated nucleic acid molecule comprising a sequence greater than 70% or greater than 95% identical to nucleotides 1238-1720 of SEQ ID NO:1 . Claims 12-13 are drawn to a vector comprising the nucleic acid molecule of claim 1 and a transformed plant cell comprising said vector.

Applicant traverses the rejection and argues that claim 1 as amended is adequately described with respect to both structural and functional properties as amended claims 1 incorporates the limitations previously found in claim 5 which was not subject to this rejection (reply page 9).

The rejection is maintained because Applicant has not described a representative number of isolated nucleic acid molecules of the genus that have both the recited structural features and a specific function correlated with those features. The rejected claims require that the isolated nucleic acid molecules encode a polypeptide that functions in meiotic cells of plants to maintain normal pairing of homologous chromosomes and that comprises an amino acid sequence greater than 70% or at least 95% identical to amino acids 361 through 521 of SEQ ID NO:2, yet the specification describes only one isolated nucleic acid molecule that meets the structural requirements of the claims (SEQ ID NO:1). Furthermore, as discussed *infra* in the rejections under 35 USC 112, second paragraph, and 35 USC 101, "functions in meiotic cells of plants to maintain normal pairing of homologous chromosomes" is neither a definite nor a specific function. Additionally, while the claim recites structural features common to members of the genus, the correlation between those structural features and a specific function is not described.

Claims 1-8 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed April 25, 2003.

Applicant's arguments filed September 26, 2003, have been fully considered but they are not persuasive.

Claims 1-3 and 5 as amended are now drawn to isolated nucleic acid molecules encoding a polypeptide comprising an amino acid sequence greater than 70% or at least 95% identical to amino acids 361 through 521 of SEQ ID NO:2, and an isolated nucleic acid molecule comprising a sequence greater than 70% or greater than 95% identical to nucleotides 1238-1720 of SEQ ID NO:1 . Claims 12-13 are drawn to a vector comprising the nucleic acid molecule of claim 1 and a transformed plant cell comprising said vector.

Applicant traverses the rejection and points out that the claims as amended are directed to nucleic acids having a specified function, having a specified identity to SEQ ID NO:1, and encoding cyclin-domain-containing proteins having a specified identity to SEQ ID NO:2. Applicant additionally points to the disclosure of empirical evidence of a loss of protein function *in situ* by insertional disruption of the protein coding region that results in gross and fine phenotypes that are readily discernable by one skilled in the art. Applicant argues that it would not require undue experimentation for one skilled in the art apply methodologies such as antisense or cosuppression to test sequences homologous to SEQ ID NO:1 for their ability to impart the phenotypes associated with the insertional disruption of the protein coding region (reply pages 9-10).

The rejection is maintained because the specification does not provide sufficient guidance for one skilled in the art to use the claimed invention without undue experimentation. Such guidance is necessary because the application of methodologies such as antisense or cosuppression to test sequences for their ability to impart a particular phenotype is unpredictable. For example, Sandler et al. (Plant Molecular Biology, 1988, Vol. 11, No. 3, pages 301-310) teach that the ability of an antisense transcript to suppress gene expression depends on the length of the transcript and its position relative to the parent gene. When expressed as antisense transcripts, DNA fragments encoding different portions of the nopaline synthase gene vary in their ability to inhibit nopaline synthase gene expression (page 308 column 2 and Table 4, page 309 column 1 first full paragraph). Antisense transcripts downstream from the Cla I site (nucleotide 373) effectively suppressed nopaline synthase gene expression, whereas the full length antisense transcript and the antisense transcript upstream from the Cla I site (nucleotides 1 to 373) did not (id). See also van der Krol et al. (Plant Molecular Biology, 1990, Vol. 14, pages 457-466), who teach that a full length petunia chalcone synthase (CHS) cDNA, as well as CHS sequences encoding half-length or quarter-length RNA complementary to the 3' half of the CHS mRNA, decreased the expression of endogenous petunia CHS, whereas half-length RNA complementary to the 5' half of the CHS mRNA did not (page 460 Figures 1 and 2; page 461 Figure 3).

While the instant specification does disclose empirical evidence of a loss of protein function *in situ* by insertional disruption of the protein coding region of SEQ ID NO:1 that results in gross and fine phenotypic changes, the specification provides no guidance with respect to how to use an isolated nucleic acid molecule of SEQ ID NO:1 to achieve the same phenotypic

effect. Absent such guidance it would require undue experimentation for one skilled in the art to determine how to use SEQ ID NO:1, or sequences homologous thereto, to produce transgenic plants exhibiting male sterility and failure to maintain homologue attachment during meiotic prophase I. One skilled in the art would have to resort to trial and error testing of each of the claimed sequences, as well as subfragments thereof, to determine their phenotypic effect, if any, on a plant transformed therewith.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite in the recitation of the limitation "functions in meiotic cells of plants to maintain normal pairing of homologous chromosomes", describing the function of the polypeptide encoded by the claimed isolated nucleic acid molecule. It is unclear what function the encoded polypeptide performs. The specification at page 8 lines 28-30 indicates that the encoded polypeptide activates a cyclin-dependent kinase to regulate the activities of <u>other</u> proteins that maintain homolog attachment, yet the rejected claim suggests that it is the encoded protein itself that functions to maintain homolog attachment.

Claim Rejections - 35 USC § 101 and § 112

Claims 1-8 and 12-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, and under 35 U.S.C. 112, first paragraph, because one skilled in the art clearly would not know how to use the claimed invention, for the reasons of record set forth in the office action mailed April 25, 2003.

Claims 1-8 and 12-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons of record set forth in the office action mailed April 25, 2003.

Applicant's arguments filed September 26, 2003, have been fully considered but they are not persuasive.

Claims 1-3 and 5 as amended are now drawn to isolated nucleic acid molecules encoding a polypeptide comprising an amino acid sequence greater than 70% or at least 95% identical to amino acids 361 through 521 of SEQ ID NO:2, and an isolated nucleic acid molecule comprising a sequence greater than 70% or greater than 95% identical to nucleotides 1238-1720 of SEQ ID NO:1 . Claims 12-13 are drawn to a vector comprising the nucleic acid molecule of claim 1 and a transformed plant cell comprising said vector.

Applicant traverses the rejection and points out that the claims as amended are directed to nucleic acids having a specified function, having a specified identity to SEQ ID NO:1, and encoding cyclin-domain-containing proteins having a specified identity to SEQ ID NO:2.

Applicant also points to the disclosure that the encoded protein has a cyclin domain and significant homology to other known cyclins, and that other known cyclins have been found to be important for meiosis and mitosis. Applicant additionally points to the disclosure of empirical evidence of a loss of protein function *in situ* by insertional disruption of the protein coding region that results in male sterility, and argues that the ability of a nucleic acid molecule to produce a male sterile plant is a specific and substantial utility asserted in the specification, as well as a well-established utility (reply pages 11-12).

The rejection is maintained because a utility for the claimed isolated nucleic acid molecules has not been established. The examiner does not dispute that the ability of a nucleic acid molecule to produce a male sterile plant is both a specific and substantial utility and a well-established utility. The examiner maintains, however, that such a utility has not been established for the claimed isolated nucleic acids.

The examiner also does not dispute Applicant's assertion that the encoded protein has a cyclin domain and significant homology to other known cyclins, or Applicant's assertion that other known cyclins have been found to be important for meiosis and mitosis. The examiner maintains, however, that Applicant has not established that the claimed isolated nucleic acids encode a protein having a cyclin function, or a protein having a functional domain common to cyclins known to have a specific role in the maintenance of homologous chromosome pairing in meiotic cells. Establishment of a function empirically or by specific correlation is necessary because cyclins are a large class of proteins possessing structural and functional differences as well as similarities. Not all cyclins would be expected to produce the type of phenotypic effects observed upon the insertional disruption of the protein coding region of SEQ ID NO:1, as

different types of cyclins are associated with different phases of mitosis and meiosis. See for example Swaminathan et al. (Plant Physiology 2000, Vol. 124, pages 1658-1667), who teach that *Arabidopsis* plants homozygous for the insertional disruption of a D-type cyclin gene associated with the G1 phase of the cell cycle do not exhibit any obvious mutant phenotype (page 1662 column 2 third full paragraph).

Additionally, the rejected claims do not require that the protein encoded by the claimed isolated nucleic acid molecule have a specific function that has a specific and substantial or well established utility, such as the ability to activate a cyclin-dependent kinase or the ability to impart male sterility on a plant transformed therewith. The rejected claims require only that the encoded protein "functions in meiotic cells of plants to maintain normal pairing of homologous chromosomes". Such a function has neither a specific and substantial or a well established utility.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
December 2, 2003

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